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**REMARKS**

Applicants thank Examiner Cabrera for her comments and have carefully considered the same. It is noted that the specification and claims are amended herein.

It is noted that this submission is being filed concurrently with a responsive amendment under 37 C.F.R. §1.121. The enclosed substitute specification, submitted under 37 C.F.R. §§1.121 and 35 USC §112, replaces the previous specification with a format conforming to the requirements of the US Patent Office. No new matter has been added. The marked-up version noted herein includes those amendments provided in the second preliminary amendment filed November 21, 2003.

Applicants believe they have responded to each and every concern raised this first time by the Examiner but remain flexible should additional clarification be requested to aid the public based upon the difficult translation. It is noted that no art-related rejections or objections were raised in the instant action and may be later introduced.

Applicants provide the following detailed comments regarding the Examiner's noted areas concerns.

Regarding the concern (on page 2, last para.) involving a computer; support for a process or method involving a computer is found within the original abstract, as well as within the understanding that all automated devices (the scanner, the data processor, the milling machine, etc.) are automated by a computer processor. Use of a computer and a milling machine is directly noted in the Abstract avoiding antecedent concerns.

Regarding the concern (on page 2, last 3 lines of the page) involving the manner in which transmitted data is transmitted from a scanner to a computer, the specification has been amended to provide an antecedent basis for the well known (and subsumed) computer connection means for receiving and transmitting including via "a direct connection, an internet connection, and a removable media connection." Support for

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such an amendment is drawn from the very broad phrase "data processing connection for transmitting...." in the Abstract, the descriptions of the related art, and the required (and hence fully subsuming) operational elements to conduct the method discussed. However, this limitation is not required and has been removed for simplicity.

Regarding the concern (on page 3, second line) involving a patient's neurological therapy; support for this phrase is now found within the a description which describes the particular treatment (page 4 second para. of the translation) of free nerve endings. As the treatment of nerves is referred to as neurological therapy, and as the treatment (page 5 of the translation) of a patient's nerve-based predisposition involves neurological therapy it is proposed that sufficient support now exists for those of skill in the relevant art to understand the claim language phrase

Regarding the concern (on page 3 end of first para.) with the types of data; support is located in the translation on page 5 lines 5-6 "shape and or size [e.g., dimension], imprints, colorations, stickers, embossing [e.g., surface texture]" and in the paragraph amended into the specification in the second preliminary amendment "slope" and "contour" are noted and near-net final form is now within the related description flows. Of course, those of skill in the art recognize that the milling operation initially achieves a near-net form that is later refined to achieve the noted final form.

Regarding the concern (on page 3, second para.) involving the phrase "patient's/therapeutic predisposition" this phrase is introduced in the specification involving (page 4 first and second para.) by the use of "patient" medical disorders including flatfoot, splayfoot, clubfoot, ..... as well as the treatment [a/k/a therapeutic action] of "body balance" by placement by a trained medical professional to achieve the treatment. However, the manner in which a medical professional makes such a therapeutic decision on whether or not or where to place such preceptors (or the decision making process to select their size, shape, surface texture, etc.) is not the subject of the present patent, which is focused instead on the arrangement or method for quickly

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producing an insole based on such a pre-existing medical decisions that an insole is medically required and includes the provisions (size, shape, texture, etc.) of such descriptions on the bottom of each preceptor and orientation thereof. As consequence, it is proposed that there no need under § 112 to provide such meets and bounds for medical decision making, and hence there is no need for such recitation of the same within the specification which, instead, requires only the existence of such a decision and the generation of insoles based upon this decision. The preceptor insoles are milled according to the data gathered without further need of intervention between scanning and milling.

Finally, it is noted that the second preliminary amendment (page 2) provided for the incorporation by reference of the entire parent disclosure and provided support for the types of labels (markings and orientations) placed on the underside of the preceptors for scanning. Those markings may be, for example, the orientation, degree, slope, contour of a support pad and the amount of pressure placed on the foot.

Regarding the drawings, it is requested that the Examiner confirm the acceptability of the drawings (Figs. 1 and 2) on a single page in any subsequent communication.

While no fees are believed due with this submission, other than those extension fees enclosed herewith, should additional fees be due or the return of over payments necessary, authority is provided to access Deposit Account No. 10-0100

In the spirit of condensed and streamlined practice, if the Examiner believes that a telephone conference would be of value, the Examiner is respectfully requested to call the undersigned counsel for a prompt response.

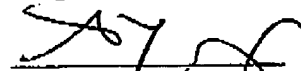
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Early and favorable action on the merits is respectfully requested in view of the enclosed amendments.

Respectfully Submitted,



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Date:- August 23, 2006

MERTE.Y3-13 SUB SPEC.DOC

Attached:

Clean version (without markings) under 37 C.F.R. §1.125(c).

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**IN THE SPECIFICATION:**

Please amend the previous specification (as last amended on November 21, 2003) as shown and, as required, a clean version of the specification is attached below.

**~~Arrangement and method for producing therapeutic insoles~~**

~~———— This application claims priority from DE 103 46 952.4 filed October 9, 2003~~

**~~SELECTED FIGURE FOR PUBLICATION~~**

~~———— Figure 2~~

**~~Description~~**

~~The present invention relates to an arrangement and a method for producing therapeutic insoles with the characteristics of the generic part of Claim 1.~~

~~It is known in prior art to produce orthopedic insoles with the aid of a computer. Thus, EP 0 284 922 A2 suggests that the patient stands on a foot imprint unit consisting of pressure-sensitive measuring elements transmitting pressure to a sensor unit which converts them into digital signals to be processed by a computer. The computer can also have stored additional information, and a shoe insole calculated from both sources can compensate for any existing defect. The data are converted into manufacturing data for a profiling tool. EP 0 317 591 B1 discloses a measuring arrangement for dynamic~~

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~~measuring where the patient walks across the measuring arrangement. In that case, too, the pressure force distribution pattern is digitized and compared by computer with a set value. Control signals for an arrangement for producing insoles are derived from the result. DE 94 00 979 U shows an assembly for the production of therapeutic insoles which X-rays the foot under stress and at rest and then scans the foot with hydraulic or pneumatic sensor elements. The resulting data are also converted into manufacturing data for insoles. Finally, DE 44 04 695 C2 discloses a method for acquiring geometric data of a foot by means of measuring soles, a blue print or a manually produced orthopedic insole. The data are given to a data processor in which a number of measurements of prefabricated blanks is stored. From the data sets, the operator can determine the desired form of the insole and decide which blank is to be used. The data are then converted further into manufacturing signals for a milling machine.~~

~~All the above named arrangements and methods proceed from measuring the nature of the foot to produce the appropriate insoles which are made to react passively to certain foot disorders such as flatfoot, splayfoot, clubfoot, pes valgus, pes adductus congenitus, etc.~~

~~However, feet are also the subject of other forms of therapy such as acupressure, reflexology, neurological stimulation, etc. Insoles have also been suggested already for these purposes. They were formed such that certain receptors under the feet were stimulated to treat problems of body balance. In contrast to the above mentioned orthopedic insoles, such hand made or cast insoles have an active, stimulating effect. A special form is the stimulation of the so-called proprioceptors, i.e. the free nerve endings of the muscles whose impulses together with those of the labyrinth (the organ governing balance) provide the brain with the necessary information about body posture.~~

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~~It is therefore the object of the present invention to create an arrangement and a method for facilitating an automated process from a determination of the suitable form and positioning of stimulators for the proprioceptors in the sole of the foot to the manufacture of insoles derived from these.~~

~~This object is achieved with the characteristics of the generic part of Claim 1. Further developments and advantageous embodiments are described in the sub-claims.~~

~~The invention relates to an arrangement for producing therapeutic insoles consisting of a platform with a scanner for scanning the undersides of a patient's foot, a data transmission for transmitting the scanned image to a computer, a data processing program which converts the transmitted data to working instructions for controlling a milling machine, and said milling machine which in accordance with the working instructions mills a therapeutic insole from a blank, characterized in that neurological preceptors are arranged in accordance with the patient's predisposition on the scanner under the patient's foot which assumes a predetermined orientation, that the preceptors belong to a set of standardized preceptors of various sizes, that the preceptors are marked, for example on their underside, and that the scanned image contains the markings and the orientation of the preceptors. In this context, preceptors are geometrically defined stimulators which act upon the proprioceptors in the sole of the foot. The marking of the preceptors can take the form of shape and/or size or of imprints, coloration, stickers, embossings, etc.~~

~~Thus, the markings and the orientation of the preceptors represent the information the computer needs for the conversion into working instructions for controlling the milling machine.~~

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~~It should be understood, that in addition to the discussion herein, those skilled in the art will recognize that the present invention enables preceptors to be arranged in a manner that accommodates a patient's predisposition, foot position, or medical condition. In this manner, the present invention enables compensating, and where possible correcting a wide variety of patient concerns. These patient concerns include the treatment of birth defects, extra or missing toes, joint (ankle, knee, hip, spine) defects or misalignments or injuries, in addition to meeting surgical and rehabilitation needs. Examples of these needs may include the creation of custom insoles to accommodate a patient's missing or weakened toes, bone loss or disease, or the need to stimulate growth and healing through accommodation of selected proprioceptors. The present invention enables automatic accommodation to include the precise selection of amount, degree, slope, and contour of the pressure placed on the proprioceptors and facilitates an simple determination and manipulation of the same.~~

~~It should additionally be understood, that in support of the disclosure and discussion herein, the entire contents of the parent application, DE 103 45 952.4, as filed on October 9, 2003 are incorporated herein by reference.~~

~~The invention also relates to a method for producing a therapeutic insole consisting of the following steps:~~

- ~~5. Method of producing a therapeutic insole, consisting of the following steps:~~
- ~~—Preparing a platform with a scanner for the underside of the patient's foot;~~
  - ~~—Aligning the patient's foot position in accordance with a predetermined orientation;~~
  - ~~—Arranging preceptors marked on the underside under the patient's foot according to a predisposition of the patient;~~
  - ~~—Scanning the underside of the patient's foot with the preceptors arranged under it;~~
  - ~~—Transmitting the scanned image to a computer;~~



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~~—Converting the information of the image by the computer into working instructions for controlling a milling machine, whereby the computer is programmed with computing steps representing the respective markings and the orientation of the preceptors;~~  
~~—Milling the therapeutic insoles from prefabricated blanks in accordance with the working instructions;~~  
~~—whereby the working instructions are substantially based on the processing of the markings and the orientation of the preceptors and whereby not only the contours of the therapeutic insole, but also the dimensions of the preceptors are milled out.~~

~~There is an automatic sequence between the scanning and milling steps. It is not necessary for the operators to intervene in data processing.~~

~~Below, the invention is described in detail by means of practical examples, with reference to the drawings, where~~

~~Fig. 1 is a schematic view of a scanned image;~~

~~Fig. 2 is a schematic view of the configuration of preceptors on a therapeutic insole.~~

~~The scanned image of Fig. 1 shows a foot 2 resting on a transparent plate 1' of a 2-D scanner 1. The contour lines 6 and 7 represent a coarser and a closer auxiliary line for covering the current position of the foot and its proportions. Two preceptors 3, 4 are placed under the foot 2. The preceptors consist of a rigid material such as cork or a strong plastic. The preceptors are configured by skilled personnel according to certain predispositions of the patient's body posture. Then, the foot with the preceptors is scanned, and the image containing information about the proportions of the foot and the type and orientation of the preceptors is converted into data that can be processed by a~~

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~~computer (not shown). The computer turns these data into working instructions for a milling machine (not shown) which follows these instructions to cut the insole 5 (as in Fig. 2) from a blank. No technician has to intervene in the step in which the data of the scanned image are evaluated and converted into working instructions for the milling machine; no corrections are necessary, and no blanks have to be adapted. The view in Fig. 2 shows only the preceptors 3' and 4', which have been cut out by the milling machine. Of course, the finished insole can include other contours such as a foot bed. Preferably, the insole consists of an industrial plastic foam such as E/VA that is covered with a microfiber material.~~

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**Abstract**

~~Arrangement for producing therapeutic insoles, consisting of a platform with a scanner for scanning the undersides of the patient's feet, a data processing connection for transmitting the scanned image to a computer, a data processing computer program which converts the transmitted data into working instructions for the control of a milling machine, and of said milling machine which mills a therapeutic insole from a blank according to said working instructions;~~

~~whereby neurological preceptors are placed on the scanner under the patient's foot in accordance with the patient's predisposition, whereby the preceptors are part of a set of standardized preceptors having various dimensions, whereby the preceptors are identified by markings on their underside, and whereby the scanned image contains the identifying markings and the orientation of the preceptors.~~

(Fig. 2)

**ARRANGEMENT AND METHOD FOR PRODUCING THERAPUTIC  
INSOLES****CROSS REFERENCE TO RELATED APPLICATIONS**

This application claims priority from DE 103 46 952.4, filed October 9, 2003,  
the entire contents of which are incorporated herein by reference.

**SELECTED FIGURE FOR PUBLICATION**

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Figure 2**BACKGROUND OF THE INVENTION****1. Field of the Invention**

The present invention relates to an arrangement and method for producing therapeutic insoles.

**2. Description of the Related Art**

It is known in prior art to produce orthopedic insoles with the aid of a computer. Thus, EP 0 284 922 A2 suggests that the patient stands on a foot imprint unit consisting of pressure-sensitive measuring elements transmitting pressure to a sensor unit which converts them into digital signals to be processed by a computer. The computer can also have stored additional information, and a shoe insole calculated from both sources can compensate for any existing defect. The data are converted into manufacturing data for a profiling tool.

EP 0 317 591 B1 discloses a measuring arrangement for dynamic measuring where the patient walks across the measuring arrangement. In that case, too, the pressure force distribution pattern is digitized and compared by computer with a set value. Control signals for an arrangement for producing insoles are derived from the result.

DE 94 00 979 U shows an assembly for the production of therapeutic insoles which X-rays the foot under stress and at rest and then scans the foot with hydraulic or pneumatic sensor elements. The resulting data are also converted into manufacturing data for insoles.

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Finally, DE 44 04 695 C2 discloses a method for acquiring geometric data of a foot by means of measuring soles, a blue-print or a manually produced orthopedic insole. The data are given to a data processor in which a number of measurements of prefabricated blanks are stored. From the data sets, the operator can determine the desired form of the insole and decide which blank is to be used. The data are then converted further into manufacturing signals for a milling machine.

All the above named arrangements and methods proceed from measuring the nature of the foot to produce the appropriate insoles which are made to react passively to certain foot disorders such as flatfoot, splayfoot, clubfoot, pes valgus, pes adductus congenitus, etc.

However, feet are also the subject of other forms of therapy such as acupressure, reflexology, neurological stimulation, etc. Insoles have also been suggested already for those purposes. They were formed such that certain receptors under the feet were stimulated to treat problems of body balance. In contrast to the above mentioned orthopedic insoles, such hand-made or cast insoles have an active, stimulating effect. A special form is the stimulation of the so-called proprioceptors, i.e. the free nerve endings of the muscles whose impulses together with those of the labyrinth (the organ governing balance) provide the brain with the necessary information about body posture.

Accordingly, there is a need for an improved arrangement and method for producing therapeutic insoles overcoming at least one of the detriments noted above.

### **OBJECTS AND SUMMARY OF THE INVENTION**

It is an object of the present invention to create an arrangement and a method for facilitating an automated process from a determination of the suitable form and positioning of stimulators for the proprioceptors in the sole of the foot to the manufacture of insoles derived from these.

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The invention relates to an arrangement for producing therapeutic insoles consisting of a platform with a scanner for scanning the undersides of a patient's foot, a data transmission for transmitting the scanned image to a computer, a data processing program which converts the transmitted data to working instructions for controlling a milling machine, and said milling machine which in accordance with the working instructions mills a therapeutic insole from a blank, characterized in that neurological preceptors are arranged in accordance with the patient's predisposition on the scanner under the patient's foot which assumes a predetermined orientation, that the preceptors belong to a set of standardized preceptors of various sizes, that the preceptors are marked, for example on their underside, and that the scanned image contains the markings and the orientation of the preceptors. In this context, preceptors are geometrically defined stimulators which act upon the proprioceptors in the sole of the foot. The marking of the preceptors can take the form of shape and/or size or of imprints, coloration, stickers, embossings, etc.

Thus, the markings and the orientation of the preceptors represent the information the computer needs for the conversion into working instructions for controlling the milling machine.

It should be understood, that in addition to the discussion herein, those skilled in the art will recognize that the present invention enables preceptors to be arranged in a manner that accommodates a patient's predisposition, foot position, or medical condition. In this manner, the present invention enables compensating, and where possible correcting a wide variety of patient concerns. These patient concerns include the treatment of birth defects, extra or missing toes, joint (ankle, knee, hip, and spine) defects or misalignments or injuries, in addition to meeting surgical and rehabilitation needs. Examples of these needs may include the creation of custom insoles to accommodate a patient's missing or weakened toes, bone loss or disease, or the need to stimulate growth and healing through accommodation of selected proprioceptors. The

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present invention enables automatic accommodation to include the precise selection of amount, degree, slope, and contour of the pressure placed on the proprioceptors and facilities a simple determination and manipulation of the same.

The invention also relates to a method for producing a therapeutic insole consisting of the following steps:

- Preparing a platform with a scanner for the underside of the patient's foot;
- Aligning the patient's foot position in accordance with a predetermined orientation;
- Arranging preceptors marked on the underside under the patient's foot according to a predisposition of the patient;
- Scanning the underside of the patient's foot with the preceptors arranged under the foot;
- Transmitting the scanned image to a computer via at least one of a direct connection, a network connection, and internet connection, a wired connection, a wireless connection, and a removable media connection;
- Converting the information of the image by the computer into working instructions for controlling a milling machine, whereby the computer is programmed with computing steps representing the respective markings and the orientation of the preceptors;
- Milling the therapeutic insoles from prefabricated blanks in accordance with the working instructions into near-net final and final form; whereby the working instructions are substantially based on the processing of the markings and the orientation of the preceptors and whereby not only the contours of the therapeutic insole, but also the dimensions of the preceptors are milled out.

There is an automatic sequence between the scanning and milling steps. It is not necessary for the operators to intervene in data processing based on the initial scan.

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In sum, the present invention relates to an arrangement for producing therapeutic insoles, consisting of a platform with a scanner for scanning the undersides of the patient's feet, a data processing connection for transmitting the scanned image to a computer, a data processing computer program which converts the transmitted data into working instructions for the control of a milling machine, and of said milling machine which mills a therapeutic insole from a blank according to said working instructions, whereby neurological preceptors are placed on the scanner under the patient's foot in accordance with the patient's predisposition, whereby the preceptors are part of a set of standardized preceptors having various dimensions, whereby the preceptors are identified by markings on their underside, and whereby the scanned image contains the identifying markings and the orientation of the preceptors.

The above and other objects, features and advantages of the present invention will become apparent from the following description read in conjunction with the accompanying drawings, in which like reference numerals designate the same elements.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

Fig. 1 is a schematic view of a scanned image.

Fig. 2 is a schematic view of the configuration of preceptors on a therapeutic insole.



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**DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

Reference will now be made in detail to several embodiments of the invention that are illustrated in the accompanying drawings. Wherever possible, same or similar reference numerals are used in the drawings and the description to refer to the same or like parts or steps. The drawings are in simplified form and are not to precise scale or shape. For purposes of convenience and clarity only, directional terms, such as top, bottom, up, down, over, above, and below may be used with respect to the drawings. These and similar directional terms should not be construed to limit the scope of the invention in any manner

The scanned image of Fig. 1 shows a foot 2 resting on a transparent plate 1' of a 2-D scanner 1. The contour lines 6 and 7 represent a coarser and a closer auxiliary line for covering the current position of the foot and its proportions. Two preceptors 3, 4 are placed under the foot 2. The preceptors consist of a rigid material such as cork or a strong plastic. The preceptors are configured by skilled personnel according to certain predispositions of the patient's body posture.

Then, the foot with the preceptors is scanned, and the image containing information about the proportions of the foot and the type and orientation of the preceptors is converted into data that can be processed by a computer (not shown). The computer turns these data into working instructions for a milling machine (not shown) which follows these instructions to cut the insole 5 (as in Fig. 2) from a blank. No technician has to intervene in the step in which the data of the scanned image are evaluated and converted into working instructions for the milling machine; no corrections are necessary, and no blanks have to be adapted.

The view in Fig. 2 shows only the preceptors 3' and 4', which have been cut out by the milling machine. Of course, the finished insole can include other contours such

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as a foot bed. Preferably, the insole consists of an industrial plastic foam such as E/VA that is covered with a microfiber material.

In the claims, means- or step-plus-function clauses are intended to cover the structures described or suggested herein as performing the recited function and not only structural equivalents but also equivalent structures. Thus, for example, although a nail, a screw, and a bolt may not be structural equivalents in that a nail relies on friction between a wooden part and a cylindrical surface, a screw's helical surface positively engages the wooden part, and a bolt's head and nut compress opposite sides of a wooden part, in the environment of fastening wooden parts, a nail, a screw, and a bolt may be readily understood by those skilled in the art as equivalent structures.

Having described at least one of the preferred embodiments of the present invention with reference to the accompanying drawings, it is to be understood that the invention is not limited to those precise embodiments, and that various changes, modifications, and adaptations may be effected therein by one skilled in the art without departing from the scope or spirit of the invention as defined in the appended claims.

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**ABSTRACT OF THE DISCLOSURE**

The present invention relates to an arrangement for producing therapeutic insoles, consisting of a platform with a scanner for scanning the undersides of the patient's feet, a data processing connection for transmitting the scanned image to a computer, a data processing computer program which converts the transmitted data into working instructions for the control of a milling machine, and of said milling machine which mills a therapeutic insole from a blank according to said working instructions, whereby neurological preceptors are placed on the scanner under the patient's foot in accordance with the patient's predisposition, whereby the preceptors are part of a set of standardized preceptors having various dimensions, whereby the preceptors are identified by markings on their underside, and whereby the scanned image contains the identifying markings and the orientation of the preceptors.